

FORM PTO 1449 (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		ATTY DOCKET NO. 5045-56103USCIP		APPLICATION NO. 08/960,517			
		RECEIVED JAN 04 2005 OFFICE OF PETITIONS		APPLICANT Eugenio Cefali, et al. FILING DATE 31 October 1997 GROUP 1615			
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO/ OR ABSTRACT
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)							
DOCUMENTS SUBMITTED UNDER MPEP § 724							
		Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004) ✓ - Subject to Protective Order					
		Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version] ✓ - Subject to Protective Order					
		Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004) ✓ - Subject to Protective Order					
		Expert Report of Dr. Sergio Fazio Regarding U.S. Patent No. 6,676,967 (August 17, 2004) ✓ - Subject to Protective Order					
		Expert Report of Don W. Martens (February 6, 2004) [Redacted Version] ✓ - Subject to Protective Order					
		Expert Report of Don W. Martens Regarding U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version] ✓ - Subject to Protective Order					
		Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version] - Subject to Protective Order					
		Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 6,676,967 (August 18, 2004) ✓ - Subject to Protective Order					
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FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/960,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		APPLICANT Eugenio Cefall, et al. RECEIVED	
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OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
DOCUMENTS SUBMITTED UNDER MPEP § 724			
		Rebuttal Expert Report of Thomas S. Foster, Pharm.D. (April 2, 2004) ✓ - Subject to Protective Order	
		Rebuttal Expert Report of Thomas S. Foster, Pharm.D. Regarding The '967 Patent (October 4, 2004) ✓ - Subject to Protective Order	
		Rebuttal Expert Report of James W. McGinity, Ph.D. (April 2, 2004) ✓ - Subject to Protective Order	
		Supplemental Rebuttal Expert Report of James W. McGinity, Ph.D. (August 18, 2004) ✓ - Subject to Protective Order	
		Rebuttal Expert Report of James W. McGinity, Ph.D. Regarding The '967 Patent (September 30, 2004) ✓ - Subject to Protective Order	
		Expert Report of Mark E. McGovern, M.D. (February 6, 2004) ✓ - Subject to Protective Order	
		Expert Report of Mark E. McGovern, M.D. (August 20, 2004) ✓ - Subject to Protective Order	
		Expert Report of Frank M. Sacks, M.D. (April 2, 2004) ✓ - Subject to Protective Order	
		Expert Report of Frank M. Sacks, M.D. (August 20, 2004) ✓ - Subject to Protective Order	
		Rebuttal Expert Report of Mary Ann Tucker, Esq. (April 2, 2004) ✓ - Subject to Protective Order	
		Rebuttal Expert Report of Mary Ann Tucker, Esq. Regarding The '967 Patent (October 1, 2004) ✓ - Subject to Protective Order	

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DOCUMENTS SUBMITTED UNDER MPEP § 724			
		Sample Kos Clinical Trial Medical Consent Form - Subject to Protective Order ✓	
		Sample Kos Clinical Trial Investigator's Statement - Subject to Protective Order ✓	
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	Excerpts from the 1993, 2000 and 2002 editions of the Physician's Desk Reference ✓ 1993 edition (pp. 434, 611, 856, 1189, 1919, 1920, 2491 and 2492) 2000 edition (pp. 1519-1523) ✓ 2002 edition (pp. 1846-1850) ✓
	<i>Niacin: Double-edged Sword for Lowering Cholesterol</i>, Tufts University Diet & Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6 ✓
	Larsen, ML and Illingworth, DR, <i>Drug Treatment of Dyslipoproteinemia</i>, Med Clin N Am., 78:225-245 (1994) ✓
	Lavie, Letter to Editor, JAMA 1994; 272:513-515 ✓
	Keenan, Letter to Editor, JAMA 1994; 272:513-515
	Shields & Beckmann, Letter to Editor, JAMA 1994; 272:513-515
	Thomas N. Tozer, <i>Clinical Pharmacokinetics Concepts and Applications</i> (3d ed. 1995) at Chapter 9, p. 120 ✓
	Excerpts from the 1995 United States Pharmacopeia (pp. iii-vi, 1080-1082, 1793-1799, 1940-1944) ✓
	Morgan & Capuzzi Abstract, <i>Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin</i>, Clinical Pharmacology & Therapeutics (February 1996) ✓
	Morgan & Capuzzi Article, <i>Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial</i>, J. Cardiovasc. Pharmacol. Therapeut. 1(3):195-202 (July 1996) ✓

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OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
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		Guyton JR, <i>Advances in Dyslipidemia: Discussion Session II</i>, Am J Cardiol, 1998: 82(12A): 85U-86U ✓	
		Knopp RH, et al., <i>Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia</i>, Metabolism 47:1097-1104 (1998) ✓	
		American Diabetes Association: <i>Management of Dyslipidemia in Adults with Diabetes</i>, Diabetes Care 21:179-182, 1998 ✓	
		Elam MB, et al., <i>Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease</i>, JAMA: 2000; 284:1263-1270 ✓	
		Kesala R, et al., <i>Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP)</i>, Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000) ✓	
		2001 NCEP Report at VI-11, Table VI.2-3 ✓	
		Wang, W. et al., <i>Effect of Nicotinic Acid Administration on Hepatic Very Low Density Lipoprotein-Triglyceride Production</i>, Am J Physiol Endocrinol Metab., 280:E540-E547 (2001) ✓	
		Smith SC, et al., <i>AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update</i>. AHA/ACC Scientific Statement, 1577-79 ✓	
		Tavintharan S and Kashyap M, <i>The Benefits of Niacin in Atherosclerosis</i>, Curr Athero. Reports 2001; 3:74-82 ✓	
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		Grundy SM, et al., <i>Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes</i>. Arch Intern Med. 2002; 162: 1568-1576 ✓
		American Diabetes Association: <i>Management of Dyslipidemia in Adults with Diabetes</i>, Diabetes Care 25:S74-S77, 2002 ✓
		Pan J, et al., <i>Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabetes, Diabetes, Obesity and Metabolism</i> 4:255-261 (2002) ✓
		Pan J, et al., <i>Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes</i>, Metabolism 51:1120-1127 (2002) ✓
		Meyers CD, et al., <i>Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia</i>, Ann Intern Med. 2003; 139:996-1002 ✓
		CDER Guidance for Industry, <i>Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations</i> (March 2003) ✓
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Form #62

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